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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,985	11/24/2003	Peter Michel	14306.01	3362
David E. Bruhn DORSEY & WHITNEY LLP Intellectual Property Department, Suite 1500 50 South Sixth Street Minneapolis, MN 55402-1498			EXAMINER BHATIA, AARTI	
			ART UNIT 3763	PAPER NUMBER
			MAIL DATE 09/03/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/720,985

Applicant(s)

MICHEL, PETER

Examiner

Aarti Bhatia

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 April 2008 and 22 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41, 43 and 45-48 is/are pending in the application.
- 4a) Of the above claim(s) 1-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40, 41, 43, and 45-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This is the second Office Action based on the 10/720,985 application filed on 11/24/2003. Claims 1-48, as amended on 5/22/2008, are currently pending and have been considered below.

Response to Amendment

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 40, 41, 43, and 46-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Young et al (US Patent 5,788,673).

With respect to claim 40, Young et al teach a first volume (figure 2, (162)), and a second volume (figure 2, (164)), wherein the volumes are adapted to contain a fluid (figure 2, (166)), placing the volumes in fluid communication (figure 2, (172) and column 8, lines 27-30), fluid medium can be passed from chamber 162 (thereby decreasing the volume of the first volume) into chamber 164 (thereby causing the amount of fluid in the second volume to increase) (column 8, lines 28-30), wherein the first volume is decreased by urging a first piston (figure 3, (156)), against the first volume (column 8, lines 19-22); and wherein the increasing second volume (figure 5, (164)), acts against a second piston (figure 5, (152); column 6, lines 25-26). Once the volume is transferred

from chamber 162 to chamber 164, the increased volume of 164 causes piston 152 to move forward (column 8, lines 60-63); which increases the volume of the second volume and causes the administration of injectable product from the reservoir (column 8, lines 60-63),

With respect to claim 41, Young et al teach that the fluid is a liquid (abstract, line 25).

With respect to claim 43, Young et al teach that a spring (figure 3, (176)) urges the first piston (column 7, lines 7-8).

With respect to claim 46, Young et al teach that the second piston (figure 5, (152)), has a piston rod (figure 5, (154)), operably coupled to a third piston (figure 5, (26)) 26 represents the plunger of syringe 22, displaceable through the reservoir (figure 5, (24)), and in contact with the injectable product. The present application teaches that the third piston can be any delivering means suitable for delivering the product, the plunger of Young et al fulfills this requirement.

With respect to claim 47, Young et al inherently teach a pressure differential between the first volume and the second volume when the first volume is being decreased, since there needs to be a pressure differential for the fluid to move from one volume to the other.

With respect to claim 48, Young et al teach an injection pen or syringe casing generally enclosing said volumes (figure 1, (121); column 5, lines 50-55).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Young et al in view of Tountas (US Patent 4,773,419).

Young et al fail to describe the contact area between the piston and the fluid.

Tountas teaches that the piston area in an injection device is related to the pressure that it generates (column 4, lines 40-45). Young et al show a piston area 156 in contact with fluid 166 in volume 162. It is inherent from Young et al that the force of the first volume is greater than that of the second volume since the force of the first piston 156 on the first volume 162 is what drives the second volume 164 to act on the second piston 152. It would have been obvious to include different piston areas so that the area of contact between the first piston and the fluid in the first volume is larger than an area of contact between the second piston and the fluid in the second volume, to

generate different pressures. This would achieve the result of Young et al., whereby the force of the first piston on the first volume acts to increase the second volume, which then acts on the second piston to drive a third piston to deliver the injectable product.

Response to Arguments

5. Applicant's arguments filed 4/25/2008 have been fully considered but they are not persuasive.
6. The Applicant argues that Claim 40 is not anticipated by Young. The Examiner disagrees. Although the inventions of the present application and of Young function differently, the device of Young still meets the limitations of Claim 40, as currently presented.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aarti Bhatia whose telephone number is (571) 270-5033. The examiner can normally be reached on Monday-Thursday 8:00am - 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call (800) 786-9199 (IN USA OR CANADA) or (571) 272-1000.

/Aarti Bhatia/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
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